

REMARKS

In the Office Action mailed from the United States Patent and Trademark Office on January 24, 2007, claims 1, 5-12, and 24-26 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement; claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) and further in view of Gagnon (1997); in view of Elliot (U.S. Pat. No. 1,885,401) claim 1, 4-12 and 24-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Chye (8/10/1999) in view of Schechter (1998) in view of Gagnon (1997) in view of Brock et al. (1991) in view of Nahir (EP 0 555 573 A1) and in view of Elliot (US 1,885,410).

Claim Rejections under 35 U.S.C. §112

In the pending action, claims 1, 5-12 and 24-26 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant has amended independent claim1 as indicated above to read, “wherein said operating filter pressure may range from 0.1 psig to 1000 psig.” Applicant asserts that the amended claim language finds direct support in the application as originally filed and that the amendment therefore does not introduce new matter. Accordingly, Applicant respectfully requests that the section 112 rejections be withdrawn at this time.

Claim Rejections under 35 U.S.C. §103

For the reasons set forth below, Applicant submits that the prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner. Thus, Applicant’s claims are not obvious in view of the prior art references.

1) The Prior Art Fails to Teach the Claim Limitations of the Present Invention

Applicants respectfully submit that the cited references do not teach every aspect of the claimed invention, as amended. In particular, independent claim 1 A method for processing and administering and improved *Morinda citrifolia* product with increased capacity to scaveng lipid hydroperoxides and superoxide anion free radicals within the body, said method comprising: harvesting the fruit from a *Morinda citrifolia* plant; allowing fruit to ripen for 0 to 14 days; preparing said harvested fruit for extraction of the juice therefrom, wherein said preparing comprises: a) placing the ripened fruit in plastic lined containers, and b) holding the fruit in said containers for 0 to 30 days extracting the juice from said prepared fruit to obtain said *Morinda citrifolia* fruit juice, wherin said extraction comprises: a) mechanically separating seeds and peel from juice and pulp; b) filtering by centrifuge decanter with a screen filter size between 1 and 2000 microns, wherein said operating filter pressure may range from about 0.1 psig to 1000 psig combining said processed *Morinda citrifolia* product with other ingredients said dietary supplement comprising: a) a first juice from *Morinda citrifolia* fruit present in an amount between about 10 and 99.99 percent by weight; b) processed *Morinda citrifolia* pulp; c) blueberry juice concentrate; d) grape juice concentrate; e) natural flavoring; f) consuming said dietary supplement; and inhibiting lipid peroxidation.

The method of making the product and the various constitutive elements added to the product before delivery have a significant effect on lipidperoxidation inhibition. The amended claims more distinctly outline the importance of the harvesting and processing steps in order to produce an improved *Morinda citrifolia* product, which has increased capacity to inhibit Lipiberoxidation. The levels of lipidperoxidation inhibition experienced by utilizing the

products and methods of the present invention are not merely intrinsic properties of *Morinda citrifolia*.

The importance of the manufacturing steps are confirmed in the prior art cited. In particular, Chye discloses the concern that certain methods of manufacturing produce greater quality products, and that a Mr. Story and Wadsworth developed methods of harvesting, processing and bottling the juice that did not sacrifice the important effects natural ingredients. In fact, TNJ (Tahitian Noni ® Juice) out performed other noni based juices in antioxidant studies performed in connection with this application. U.S. Provisional Pat. App. No. 60/251,417 which contains the results of these experiments, is incorporated by reference in the present application.

Chye, Schechter and Gagnon fail to teach or fairly suggest the particular processing steps which produce a *Morinda citrifolia* product developed particularly to scavenge lipid hydroperoxides. Chye provides a non-enabling disclosure, which indicates that “noni-juice is the new darling of health-conscious Malaysians”. Chye indicates further however that there have been no proper trials conducted with humans for verifying the efficacy of noni. Chye continues by indicating that various noni products are likely to hit the market which raises substantial questions, “[t]his naturally leads to the question: which form is the best to take? Other nagging questions arise, which juice is of the best quality? Which manufacturer guarantees quality control in the harvesting of the fruit and the bottling of the juice? (...) Accordingly, Chye acknowledges that some noni products may be more effective than others and that some products may be dangerous to human health. But Chye fails to provide guidance for overcoming this problem, Rather, “after three years, during which time they were oblivious to Dr. Heinecke’s own research on noni, they [Stephen Story and John Wadsworth] developed a way to harvest, process and bottle the juice without sacrificing the important natural ingredients. They also

developed a way to neutralise its pungent odour and horrible taste by adding grape juice and blueberry juice.” Accordingly, Chye indicates that at the time of publication no assay had been performed which to verify efficacy of any noni product, and that nagging questions remained (e.g. which processes would allow production of a noni product without sacrificing important natural qualities), only after three years of secret development did Steven Story and John Wadsworth develop a method, secret at the time, for preserving the ingredients. Accordingly, the article Chye suggests that it is difficult to produce a noni product which maintains efficacy during processing, and that Stephen Story and John Wadsworth had developed a secret method for processing which allowed the bottling of the juice without sacrificing its important natural ingredients. Accordingly, Chye indicates that does not place into the public knowledge a process for processing the noni plant which preserves the natural efficacy of the plant during processing. But rather, indicates that Steven Story and John Wadsworth had developed and maintained a secret a process. Accordingly, Chye places the world in possession of the fact that a secret process exists, not in possession of the process for producing the product itself. Accordingly, Chye fails to teach or fairly suggest the process steps recited in the claims of the present invention.

Schechter indicates that noni fruit contains the antioxidant vitamin C and selenium plus other substances counteract inflammation and absorb free radicals in the body. However, Schetheter does not disclose processing steps claimed herein which produce the surprising scavenging properties claimed and disclosed in the present invention. The composition as recited in the claims of the present invention has a scavenging affect which exceeds the regular intake of vitamin C and other known antioxidants. Experiments conducted in support of the present application indicated that the regular intake of the product of the present invention provides a

stronger scavenging effect on super oxides and free radicals within the body than the regular intake of vitamin C, pycocogenol (Maritime pine bar extract), or grape seed powder. Specification, page 16, lines 6-15. Accordingly, while Schechter indicates that noni fruit has antioxidants, Schechter does not describe a method of processing and administering the noni fruit so as to provide a stronger scavenging effect as recited in the present invention.

As the cited references fail to disclose or suggest all of the claim limitations of independent claims of the present invention, and further fail to suggest modifying the reference as suggested by the Examiner, the present invention is not obvious in view of such references.

## 2. The References Are Not Enabling

The Federal Circuit recently reaffirmed that in order for a reference to anticipate the claims in a pending application, it must provide a certain amount of disclosure: “[t]he disclosure in an assertively anticipating reference must be adequate to enable possession of the desired subject matter.” Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research, 346 F.3d 1051, 1055 (Fed. Cir. 2003). The court referred to In re Donohue to further support this requirement: “[i]t is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it...Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not an enabling...” Id., citing In re Donohue, 766 F.2d 531, 533. Thus, in order for the cited art to anticipate or render obvious the Applicant’s claims, it must put one skilled in the art in possession of all of the claim limitations.

Chye and Schechter both indicate that Tahitian Noni juice was ingested, but neither prior art reference discloses the method for production. As noted above Chye explicitly indicates that the methods of harvest, processing and bottling are important to maintain the integrity of the

product. Accordingly, the references do not place one skilled in the art in possession of the products which are discussed, and do not place one skilled in the art in possession of all of the claim limitations of the present invention. Accordingly, Applicant respectfully requests this rejection be withdrawn.

For at least this reason, Applicant respectfully submits that the prior art does not explicitly or impliedly teach every aspect of the invention as claimed in the independent base claims. In addition, the dependent claims place further limitations on otherwise allowable subject matter. Accordingly, Applicant respectfully submits that the cited art does not teach every aspect of the claims as provided herein and therefore does not render the claims obvious as provided herein.

CONCLUSION

If any impediments to the allowance of this application for patent remain after the above amendments and remarks are entered, the Examiner is invited to initiate a telephone conference with the undersigned attorney of record.

DATED this 24 day of April, 2007.

Respectfully submitted,

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